UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,670	07/13/2001	Phillip D. Purdy	UTSD:798US	4825

32425 7590 04/20/2006

FULBRIGHT & JAWORSKI L.L.P.
600 CONGRESS AVE.
SUITE 2400
AUSTIN, TX 78701

EXAMINER	
HAN, MARK K	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/905,670	PURDY, PHILLIP D.	
	Examiner	Art Unit	
	Mark K. Han	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) *9,10,14-16 and 29-63* is/are withdrawn from consideration.

5)☒ Claim(s) *64-67* is/are allowed.

6)☒ Claim(s) *1-8,11-13,17,19,20,22,24,25,27,28,68 and 69* is/are rejected.

7)☒ Claim(s) *18,21,23 and 26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, Species II(B) in the reply filed on 09 June 2005 is acknowledged.

2. Claims 9, 10, 14-16 and 29-63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 09 June 2005.

3. Claim 1 link(s) each of the species. The restriction requirement among the linked species is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the election of species requirement as to the linked species shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement or election of species requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 4-7, 11-13, 24, 27, 68 and 69 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,379,331 to Barbut et al. (hereinafter "Barbut").

Barbut discloses a method of navigating a spinal subarachnoid space including the steps of percutaneously introducing a guidewire 66, percutaneously introducing a device 35 having a passageway capable of receiving a guidewire and advancing the device within the subarachnoid space at least more than 10 centimeters from the entry location. See Figures 1-12A and cols. 2-11. In reference to claim 11, it is asserted that when taking a cross-section of the Barbut device, a non-circular shape can result along certain portion of the device not along the tubular member.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barbut in view of U.S. Patent No. 6,328,694 to Michaeli.

Barbut discloses the claimed method steps as shown above except for the step of removing a portion of the brain. Michaeli discusses a method of performing brain surgery having a step of removing a portion of the brain. See col. 2, lines 55-65. It would have been obvious to one of ordinary skill in the art to modify the method steps disclosed by Barbut, by removing a portion of the brain, as disclosed by Michaeli, in order increase the chances of recovery for the rest of the brain.

6. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barbut in view of U.S. Patent No. 4,904,237 to Janese.

Barbut discloses the claimed method steps as shown above except for the step of flushing CSF. Janese suggests flushing CSF and removing blood products from the CSF in order to increase the chances of brain survival. See col. 2, lines 17-39. It would have been obvious to one of ordinary skill in the art to modify the method steps disclosed by Barbut by including step of removing blood from CSF in order to increase the chances of brain survival.

7. Claims 8, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barbut in view of U.S. Patent No. 6,004,262 to Putz et al. (hereinafter "Putz").

Barbut discloses the claimed method step as shown above except for the step of placing a detector in the body or an endoscope. Putz discloses the use of an endoscope to assist in the navigation through the subarachnoid space as well as using wires to detect electrical signals, a physiological property. See col. 3, line 33 through col. 5, line 30. It would have been obvious to one of ordinary skill in the art to modify the method steps disclosed by Barbut by including the

step of introducing an endoscope or detector in the body in order to assist in the navigation of the catheter system through the subarachnoid space and to determine the viability of brain tissue.

8. Claims 17 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barbut in view of U.S. Patent No. 5,423,760 to Yoon.

Barbut discloses the claimed method as shown above except for the step of applying an electric current. Yoon suggests applying an electric current, thereby forming a lesion, to the brain (in one really long run-on sentence). See col. 3, line 14 through col. 4, line 21, more specifically col. 3, line 20 and col. 3, lines 49-55. It would have been obvious to one of ordinary skill in the art to modify the method step disclosed by Barbut by including the step of applying electric current to the brain, as suggested by Yoon, in order to provide a therapeutic benefit to the patient.

9. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barbut in view of U.S. 6,233,488 to Hess.

Barbut discloses the claimed method as shown above except for the step of introducing an electrode and placing it in the body. Hess discloses introducing an electrode through a catheter and placing it in the body. See col. 8, lines 44-52. It would have been obvious to one of ordinary skill in the art to modify the method steps of Barbut by including the step of placing an electrode, as suggested by Hess, in order to provide a therapeutic benefit to the patient.

10. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barbut in view of U.S. Patent No. 5,731,284 to Williams.

Barbut discloses the claimed method as shown above including a method of delivering therapeutic material. Barbut, however, does not disclose delivering genetic material. Williams,

generally, discloses a method of delivering genetic material to treat Alzheimer's disease. It would have been obvious to one of ordinary skill in the art to modify the method steps of Barbut by including the step of placing genetic material, as suggested by Williams, in order to provide a therapeutic benefit to the patient.

Allowable Subject Matter

11. Claims 18, 21, 23 and 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. Claims 64-67 are allowed.

Response to Arguments

13. Applicant's arguments filed 27 December 2005 have been fully considered but they are not persuasive.

Applicant's argument that Barbut fails to disclose or suggest percutaneously introducing a guidewire into the spinal subarachnoid space is not convincing. Barbut clearly shows the method step of percutaneously introducing a guidewire as shown above. The rejection under 35 U.S.C. §102(e) is hereby maintained.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge

generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Applicant generally asserts that the Examiner's motivation to combine is not explicitly provided in the art used to make the rejections under 35 U.S.C. §103(a). It is known that this source of motivation or suggestion does not need to be explicitly found in the references themselves. See *In re Johnston*, 435 F.3d 1381, 1385 (Fed. Cir. 2006) ("Precedent has also recognized that '[t]he suggestion or motivation to combine references does not have to be stated expressly; rather it may be shown by reference to the prior art itself, to the nature of the problem solved by the claimed invention, or to the knowledge of one of ordinary skill in the art.") (quoting *Medical Instrumentation and Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1221-22 (Fed. Cir. 2003)). Each of the references used in the rejections under 35 U.S.C. §103(a) is in the same field of endeavor as Barbut. Using such a combination of references does not destroy the nature of any of the references.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark K. Han whose telephone number is 571-272-4958. The examiner can normally be reached on Monday to Friday, 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mkh.

Mark K. Han
Patent Examiner
Art Unit 3767

mkh
April 17, 2006

MICHAEL J. HAYES
PRIMARY EXAMINER